

REMARKS

The issues outstanding in the Office Action mailed October 11, 2007, are the priority claim and the rejections under 35 U.S.C. 112, 102 and double patenting. Claim 1 has been indicated as being allowable. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Priority Claim

It is argued, at page 2 of the Office Action, that the priority claim is denied in view of the absence of a certified translation of priority document. The Examiner's attention is directed to MPEP§201.13, which states that "an English language translation of a non-English language foreign application is not required except: (A) when the application is involved in an interference..., (B) when necessary to overcome the date of a reference relied upon by the Examiner, or (C) when specifically required by the Examiner." The present application is not involved in an interference, the priority date is not being relied upon in order to overcome a reference, and there is no reason why the Examiner needs to require a translation of the priority document. Accordingly, it is seen that the priority claim does *not* require a translation of the priority document, and priority *must* be accorded. The same is respectfully requested.

Rejections Under 35 U.S.C. 112

Claims 3-12 and 15 remain rejected under 35 U.S.C. 112, second paragraph. Applicants respectfully, albeit quite strongly, disagree with the analysis made in this rejection. It is argued that there are no steps forming a carboxylic acid salt of compound formula I from another compound in, for example, claim 3. Applicants are mystified by this rejection. Claim 3 recites, in step (a), "forming a carboxylic acid salt of the corresponding stable form of a compound of formula I." It is not understood why "forming a carboxylic acid salt" of the corresponding stable form of the compound is not a "step" in the Examiner's opinion. It is argued, also at page 2 of the Office Action, that the production form [sic, from] the step (a) is the salt (dry or powder)." Thus, it is believed that there is apparently a fundamental chemical misunderstanding of the

process of the present application and claims. To the extent that the Examiner believes that a "salt" must necessarily be a dry product, of course, such an assumption is unsupported in chemistry. It is well known that salts of carboxylic acids can exist dissolved or suspended in solution. For example, see the attached portion of an introductory college organic chemistry text. Moreover, step (b) of the claim recites acidifying an *aqueous solution* of the salt obtained after step (a). Thus, it is clear that the claim encompasses the "steps" of forming a salt and acidifying an aqueous solution of the salt product produced in (a).

Moreover, it is submitted that "forming a carboxylic acid salt", for example, by adding hydroxide ions to the corresponding acid as detailed in the attached organic chemistry text, is manifestly well known to those of skill in the art. Thus, it is submitted that, contrary to the allegations in the Office Action, actual physical steps are recited in the claims, and there is no inconsistency with the Examiner's belief that a dry powder is formed in step (a). Accordingly, withdrawal of this rejection is strongly urged.

Rejections Under 35 U.S.C. 102

Claims 13 and 14 remain rejected under 35 U.S.C. 102(b) over Brunet (WO'113). Reconsideration of this rejection is again respectfully requested.

As noted previously, claims 13 and 14, through their dependence upon claim 1, require a metastable form of the compound of formula I. Such a metastable form is not disclosed in the commonly assigned reference. However, it is argued at page 3 of the Office Action that claim 13, directed to a pharmaceutical composition, must necessarily be an aqueous solution, and thus cannot be a metastable material. Again, this analysis is not supported by valid chemistry. For example, at page 7 of the present Specification, solid formulations which are pharmaceutical compositions of a metastable compound of formula I are disclosed, including tablets and granules. Moreover, the paragraph bridging pages 7 and 8 discloses a solid composition for oral administration. Example 3 of the specification, at page 13, discloses advantages of the metastable form of the compound of the invention, where that metastable form is prepared as a powder suitable for grinding or micronization. Thus, pharmaceutical compositions clearly include solid formulations contrary to the position in the Office Action. As a result, these claims

to the metastable form are in no way anticipated over Brunet, and withdrawal of the rejection is manifestly required.

Claims 13 and 14 have also been rejected under 35 U.S.C. 102(e) over Brunet (U.S. '758). As discussed above, the reference fails to disclose the subject matter of these claims, and withdrawal of the rejection is also urged.

Double Patenting

Finally, claims 13 and 14 have also been rejected under the doctrine of obviousness-type double patenting over Brunet '758. As discussed above, the reference does not disclose the presently claimed invention, nor suggest it. Withdrawal of this rejection is also manifestly required.

The claims of the application are in condition for allowance. However, if the Examiner has any questions or comments, he or she is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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